K080134

510(K) SUMMARY

[as required by 807 92(c)]

JAN 2 3 2009

A 510k Number

B Applicant

Company name WONJIN MULSAN Co , Ltd

Address Namdong Industrial complex 10B-7L 623-6 Namchon-dong,

Namdong-gu Incheon, Korea

Tel +82 32 816 0552

Fax +82 32 816 0557

C Proprietary and Established Names WONJIN MULSAN Co , Ltd

D Regulatory Information

-Classification Class 2

-Product cord IRP

-Regulation Number 890 5650

E Intended use

The WHF-314 (POWER Q1000) device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as

Primary lymphedema,

Edema following trauma and sport injuries,

Post immobilization edema,

Venous insufficiencies,

Lymphedema

F Device Description

WHF-314 (POWER Q1000) is Used with four chamber garments for full leg, and period has its own variable duration, pressure, cycle time and gradient setting Power unit features visual operation status and fault indicators

G Substantial Equivalence Information

Predicate Device

– K915638/K013061

- TALLEY INTERMITTENT UNIT WITH CALF APPLIATOR/
  Biotouch Massage Therapy System
  -Classification Class 2

2 Comparison with predicate

Based on the above, we conclude that the Compressible Limb and Circulation Therapy Systems (WHF-314 (POWER Q1000)) are substantially equivalent to the marketed predicate device, but (WHF-314 (POWER Q1000)) exclude the arm, forearm, chest chamber and software, and do not raise any new issues of safety or effectiveness

H Standard / Guidance Document Referenced (if applicable)

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- IEC 980 2003, Graphical symbols for use in the labeling of medical devices
- IEC1041 1998, Information supplied by the manufacturer with medical devices
- ISO 13485 2003, Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14155-1 2003, Clinical investigation of medical devices for human subjects - Part 1 General requirements
- ISO 14971 2000/A1 2003, Medical devices - Application of risk management to medical devices
- IEC 60601-1 1990/A1 93/A295/A13 96, Medical electrical equipment - Part 1 General requirements for safety (IEC 60601-1 1988/A1 91/A2 95)
- IEC 60601-2-10 2000/A1 01, Medical electrical equipment - Part 2-10 Particular requirements for the safety of nerve and muscle stimulators
- IEC 60601-1-2 2001, Medical electrical equipment - Part 1 General requirements for safety - Collateral standard Electromagnetic compatibility - Requirements and tests

I Performance Characteristics (If/when applicable)

1 See the Exhibits

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2009

Wonjin Mulsan Co , Ltd
% PATS Corporation
Mr Brandon Choi
Flemington Court #155
La Mirada, California 90638

Re K080134
Trade Name Compressible Limb and Circulation Therapy System
WHF-314(POWER-Q1000)
Regulation Number 21 CFR 890 5650
Regulation Names Powered inflatable tube massager
Regulatory Class II
Product Code IRP
Dated December 28, 2008
Received January 14, 2009

Dear Mr Choi

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name Compressible Limb and Circulation Therapy System (WHF-314)

Indications for Use The WHF-314 (POWER Q1000) device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as
Primary lymphedema,
Edema following trauma and sport injuries,
Post immobilization edema,
Venous insufficiencies,
Lymphedema

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080134